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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,168	02/23/2006	Wadih Arap	UTSC:857US	5612

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EXAMINER	
NATARAJAN, MEERA	
ART UNIT	PAPER NUMBER
1643	
MAIL DATE	DELIVERY MODE
11/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,168	ARAP ET AL.	
	Examiner	Art Unit	
	MEERA NATARAJAN	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08/05/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,11-22 and 55-61* is/are pending in the application.

4a) Of the above claim(s) *2,15,20-22 and 57-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 11-14, 16-19, 55 and 56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments in the reply filed on 08/05/2008 is acknowledged and entered into the record.

2. Accordingly, Claims 1-3, 11-22, 55-61 are pending, Claims 2, 20-22 and 57-61 are withdrawn as being drawn to non-elected inventions.

3. The finality of the rejection of the last Office action mailed 06/05/2008 is withdrawn.

4. The following species have been elected:

   a. Targeting peptide: SEQ ID NO:30

   b. Therapeutic agent: pro-apoptotic agent SEQ ID NO:1

5. After further consideration the species requirement for "targeting peptide" SEQ ID NO: has been extended to include SEQ ID NO:34.

6. Claims 1, 3, 11-19, 55 and 56 will be examined on the merits.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 1,3, 11-19 are rejected under 35 U.S.C. 102(a) as being anticipated by Arap et al. (WO/2002/020723, published 03/14/2002).

9. The claims are drawn to a method of delivering an agent to a prostate cancer tissue comprising obtaining an 100 amino acid or less peptide with a cancer targeting motif that selectively binds to prostate cancer tissue, attaching a pro-apoptotic agent consisting of SEQ ID NO:1 to the peptide to form a complex and exposing said complex to a sample of prostate tissue and diagnosing prostate cancer.

10. Arap et al. teach a method of delivering an agent to a prostate cancer tissue comprising administering an isolated peptide of 100 amino acids or less, wherein said peptide is attached to a pro-apoptosis agent (SEQ ID NO:1), chemotherapeutic agent, or an imagining agent (see claims 16-24, 41, and 51 of Arap et al.). Arap et al. teach SEQ ID NO: 1, 30, and 34 (see attached alignment).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 1 ,3, 16-19, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thakur et al. (US Patent 6,395,255) in view of Ellerby et al. (WO200042973, published 07/27/2000), Campbell et al. (American J. of Pathol. Vol. 158, pp25-32, 2001) and Schally et al. (The Prostate Vol. 45, pp.158-166, 2000).

14. The claims are drawn to a method of delivering an agent to a prostate cancer tissue comprising obtaining an 100 amino acid or less peptide with a cancer targeting motif comprising SEQ ID NO:30 that selectively binds to prostate cancer tissue, attaching a pro-apoptotic agent consisting of SEQ ID NO:1 to the peptide to form a complex and exposing said complex to a sample of prostate tissue and diagnosing prostate cancer.

15. Thakur et al. teach a method of using a tumor imaging agent to detect tumors (including prostate tumors). The tumor agent is comprised of a composition containing a tumor specific sequence and a radionuclide moiety linked to the tumor specific sequence via a linker, wherein a radionuclide is complexed to radiolabeling moiety. Thakur et al. teach a reagent comprising four amino acids GAGG (SEQ ID NO: 3 and Claim 7 of Thakur et al. see attached alignment). Although, the agents of Thakur et al. also detect other tumors (colorectal), the claim language is such that any 100 amino acid or less peptide having the amino acid sequence of SEQ ID NO:30 would inherently selectively bind to prostate cancer tissue. In addition the step (c) reads on exposing the complex to a population of cells from a normal male patient. Thakur et. al. does not teach attaching a pro-apoptotic agent comprising SEQ ID NO:1 or categorizing prostate cancer as androgen-dependent or androgen-independent and expression of IL-11R

alpha in the blood vessels of said prostate cancer. These deficiencies are made up for by Ellerby et al., Campbell et al., and Schally et al.

16. Ellerby et al. teach a chimeric prostate-homing pro-apoptotic peptide that contains a prostate-homing peptide linked to an antimicrobial peptide, where the chimeric peptide is selectively internalized by prostate tissue. Ellerby et al. teach a pro-apoptotic agent comprising SEQ ID NO:1 which can be linked to prostate-homing peptides (see p. 5 last paragraph – p. 6).

17. Campbell et al. teach increased expression of interleukin-11 receptor alpha in prostate carcinoma (see abstract).

18. Schally et al. teach the use of peptide analogs in the therapy of prostate androgen-dependent or androgen-independent cancer (see abstract).

19. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to perform the method of Claim 1 with a chimeric peptide comprising the prostate-homing peptide comprising SEQ ID NO:30 taught by Thakur et al. linked to the pro-apoptotic agent comprising SEQ ID NO:1 as taught by Ellerby et al. and exposing said peptide to prostate cancer cells that have been categorized as androgen-independent or androgen-dependent and express IL-11R alpha in their blood vessels. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Thakur et al., Ellerby et al., Campbell et al., and Schally et al. because Ellerby et al. teach that the prostate-homing peptides linked to pro-apoptotic peptides induce selective toxicity in vivo in prostate cancer, Campbell et al. teach that IL-11R alpha is overexpressed in

prostate carcinoma and Schally et al. teach that the use of peptide analogs for treatment of androgen-dependent and androgen-independent prostate cancer have been effective.

20. Claims 1, 3, 11-19, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arap et al. (WO/2002/020723, published 03/14/2002) in view of Campbell et al. (American J. of Pathol. Vol. 158, pp25-32, 2001) and Schally et al. (The Prostate Vol. 45, pp.158-166, 2000).

21. The teachings of Arap et al. are presented in the 102(a) rejection set forth above. Arap et al. does not teach categorizing prostate cancer as androgen-dependent or androgen-independent and expression of IL-11R alpha in the blood vessels of said prostate cancer. This deficiency is made up for by Campbell et al. and Schalley et al.

22. The teachings of Campbell et al. and Schalley et al. are presented in the 103(a) rejection set forth above.

23. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to perform the method of taught by Arap et al. with prostate cancer cells that have been categorized as androgen-independent or androgen-dependent and express IL-11R alpha in their blood vessels. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Arap et al., Campbell et al., and Schally et al. because Campbell et al. teach that IL-11R alpha is overexpressed in prostate carcinoma and

Schally et al. teach that the use of peptide analogs for treatment of androgen-dependent and androgen-independent prostate cancer have been effective.

All other rejections of record are withdrawn in view of Applicants arguments/amendments in the reply filed on 08/05/2008.

Conclusion

24. Claims 1, 3, 11-14, 16-19, 55 and 56 are rejected.

25. No Claim is allowed.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643